

## § 1309.25

(e), (f) or (g) of this section pursuant to the procedures set forth in §§1309.43 through 1309.46 and 1309.51 through 1309.55 of this part. In considering the revocation or suspension of a person's waiver granted pursuant to paragraph (b) or (c) of this section, the Administrator shall also consider whether action to revoke or suspend the person's controlled substance registration pursuant to 21 U.S.C. 824 is warranted.

(k) Any person exempted from the registration requirement under this section shall comply with the security requirements set forth in §§1309.71–1309.73 of this part and the recordkeeping and reporting requirements set forth under parts 1310 and 1313 of this chapter.

### § 1309.25 Exemption of certain controlled substance registrants.

(a) The requirement of registration is waived for any person who distributes a product containing a List I chemical that is regulated pursuant to §1310.01(b)(28)(i)(D), if that person is registered with the Administration to manufacture, distribute or dispense a controlled substance.

(b) The requirement of registration is waived for any person who imports or exports a product containing a List I chemical that is regulated pursuant to §1310.01(b)(28)(i)(D), if that person is registered with the Administration to engage in the same activity with a controlled substance.

(c) The Administrator may, upon finding that continuation of the waiver would not be in the public interest, suspend or revoke a person's waiver pursuant to the procedures set forth in §§1309.43 through 1309.46 and 1309.51 through 1309.57. In considering the revocation or suspension of a person's waiver, the Administrator shall also consider whether action to revoke or suspend the person's controlled substance registration pursuant to 21 U.S.C. 824 is warranted.

(d) Any person exempted from the registration requirement under this section shall comply with the security requirements set forth in Sections 1309.71–1309.73 and the recordkeeping and reporting requirements set forth under Parts 1310 and 1313 of this chapter.

[60 FR 32454, June 22, 1995, as amended at 62 FR 13968, Mar. 24, 1997]

EFFECTIVE DATE NOTE: At 67 FR 14860, Mar. 28, 2002, § 1309.25 was revised, effective Apr.

## 21 CFR Ch. II (4–1–02 Edition)

29, 2002. For the convenience of the user, the revised text follows:

### § 1309.25 Temporary exemption from registration for chemical registration applicants.

(a) Each person required by section 302 of the Act (21 U.S.C. 822) to obtain a registration to distribute, import, or export a combination ephedrine product is temporarily exempted from the registration requirement, provided that the person submits a proper application for registration on or before July 12, 1997. The exemption will remain in effect for each person who has made such application until the Administration has approved or denied that application. This exemption applies only to registration; all other chemical control requirements set forth in this part 1309 and parts 1310, and 1313 of this chapter remain in full force and effect.

(b) Each person required by section 302 of the Act (21 U.S.C. 822) to obtain a registration to distribute, import, or export a pseudoephedrine or phenylpropanolamine drug product is temporarily exempted from the registration requirement, provided that the person submits a proper application for registration on or before October 3, 1997. The exemption will remain in effect for each person who has made such application until the Administration has approved or denied that application. This exemption applies only to registration; all other chemical control requirements set forth in this part 1309 and parts 1310 and 1313 of this chapter remain in full force and effect.

### § 1309.26 Exemption of law enforcement officials.

(a) The requirement of registration is waived for the following persons in the circumstances described in this section:

(1) Any officer or employee of the Administration, any officer of the U.S. Customs Service, any officer or employee of the United States Food and Drug Administration, any other Federal officer who is lawfully engaged in the enforcement of any Federal law relating to listed chemicals, controlled substances, drugs or customs, and is duly authorized to possess and distribute List I chemicals in the course of official duties; and

(2) Any officer or employee of any State, or any political subdivision or agency thereof, who is engaged in the enforcement of any State or local law relating to listed chemicals and controlled substances and is duly authorized to possess and distribute List I

chemicals in the course of his official duties.

(b) Any official exempted by this section may, when acting in the course of official duties, possess any List I chemical and distribute any such chemical to any other official who is also exempted by this section and acting in the course of official duties.

**§ 1309.27 Exemption of certain manufacturers.**

The requirement of registration is waived for any manufacturer of a List I chemical, if that chemical is produced solely for internal consumption by the manufacturer and there is no subsequent distribution or exportation of the List I chemical.

EFFECTIVE DATE NOTE: At 67 FR 14861, Mar. 28, 2002, § 1309.27 was removed, effective Apr. 29, 2002.

**§ 1309.28 Exemption of distributors of regulated prescription drug products.**

(a) The requirement of registration is waived for any person who distributes a prescription drug product containing a List I chemical that is regulated pursuant to § 1310.01(f)(1)(iv) of this chapter.

(b) If any person exempted by this section also engages in the distribution, importation or exportation of a List I chemical, other than as described in paragraph (a) of this section, the person shall obtain a registration for such activities, as required by § 1309.21 of this part.

(c) The Administrator may, upon finding that continuation of the waiver granted in paragraph (a) of this section would not be in the public interest, suspend or revoke a person's waiver pursuant to the procedures set forth in §§ 1309.43 through 1309.46 and 1309.51 through 1309.57 of this part.

[61 FR 32926, June 26, 1996]

EFFECTIVE DATE NOTE: At 67 FR 14861, Mar. 28, 2002, § 1309.28 was removed, effective Apr. 29, 2002.

**1309.29 Waiver of registration requirement for certain activities.**

(a) The requirement of registration is waived for any retail distributor whose activities with respect to List I chemi-

cals are restricted to the distribution of below-threshold quantities of a drug product that contains a List I chemical that is regulated pursuant to § 1300.02(b)(28)(i)(D) of this chapter to an individual for legitimate medical use.

(b) The requirement of registration is waived for any person whose activities with respect to List I chemicals are limited to the distribution of red phosphorus, white phosphorus, or hypophosphorous acid (and its salts) to: Another location operated by the same firm solely for internal end-use; or an EPA or State licensed waste treatment or disposal firm for the purpose of waste disposal.

(c) The requirement of registration is waived for any person whose distribution of red phosphorus or white phosphorus is limited solely to residual quantities of chemical returned to the producer, in reusable rail cars and isotainers (with capacities greater than or equal to 2500 gallons in a single container).

(d) If any person exempted under paragraph (b) or (c) of this section also engages in the distribution, importation or exportation of a List I chemical, other than as described in such paragraph, the person shall obtain a registration for such activities, as required by § 1309.21 of this part.

(e) The Administrator may, upon finding that continuation of the waiver would not be in the public interest, suspend or revoke a waiver granted under paragraph (b) or (c) of this section pursuant to the procedures set forth in §§ 1309.43 through 1309.46 and 1309.51 through 1309.57 of this part.

(f) Any person exempted from the registration requirement under this section shall comply with the security requirements set forth in §§ 1309.71–1309.73 of this part and the record-keeping and reporting requirements set forth under parts 1310 and 1313 of this chapter.

[66 FR 52674, Oct. 17, 2001]

EFFECTIVE DATE NOTE: At 67 FR 14861, Mar. 28, 2002, § 1309.29 was removed, effective Apr. 29, 2002.